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PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

TOMAS MADRO BANDARIES,

Plaintiff,

vs.

PFIZER INC., PHARMACIA CORPORATION,
and G.D. SEARLE, LLC,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-03641-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"),
 2 and G.D. Searle LLC ("Searle") (improperly captioned in Plaintiff's Complaint as "G.D. Searle,
 3 LLC") (collectively "Defendants"), and file this Answer to Plaintiff's Complaint
 4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
 8 Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally.
 9 Defendants may seek leave to amend this Answer when discovery reveals the specific time
 10 periods in which Plaintiff was prescribed and used Bextra®.

11 **II.**

12 **ANSWER**

13 **Response to Allegations Regarding Parties**

14 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but
 15 deny that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain
 16 periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States
 17 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
 18 accordance with their approval by the FDA. Defendants admit that, during certain periods of
 19 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
 20 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
 21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
 22 FDA. Defendants state that Bextra® was and is safe and effective when used in accordance
 23 with its FDA-approved prescribing information. Defendants state that the potential effects of
 24 Bextra® were and are adequately described in its FDA-approved prescribing information,
 25 which was at all times adequate and comported with applicable standards of care and law.
 26 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages,
 27 and deny the remaining allegations in this paragraph of the Complaint.

28 2. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
2 and whether Plaintiff used Bextra®, and, therefore, deny them. Defendants deny any wrongful
3 conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining
4 allegations in this paragraph of the Complaint.

5 3. Defendants admit that Pfizer is a Delaware corporation with its principal place of
6 business in New York. Defendants admit that, as the result of a merger in April 2003,
7 Pharmacia became a subsidiary of Pfizer. Defendants admit that, during certain periods of
8 time, Pfizer marketed and co-promoted Bextra® in the United States, including California,
9 Illinois, Mississippi, and Arizona, to be prescribed by healthcare providers who are by law
10 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
11 that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.
12 Defendants are without knowledge or information to form a belief as to the truth of such
13 allegations, and, therefore, deny them. Defendants deny the remaining allegations in this
14 paragraph of the Complaint.

15 4. Defendants admit that Searle is a Delaware limited liability company with its principal
16 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,
17 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
18 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged
19 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the
20 United States to be prescribed by healthcare providers who are by law authorized to prescribe
21 drugs in accordance with their approval by the FDA. Defendants deny the remaining
22 allegations in this paragraph of the Complaint.

23 5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
24 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia
25 marketed and co-promoted Bextra® in the United States, including California, Illinois,
26 Mississippi, and Arizona, to be prescribed by healthcare providers who are by law authorized to
27 prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's
28 allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are

1 without knowledge or information to form a belief as to the truth of such allegations, and,
2 therefore, deny them. Defendants deny the remaining allegations in this Paragraph of the
3 Complaint.

4 **Response to Allegations Regarding Jurisdiction and Venue**

5 6. Defendants are without knowledge or information to form a belief as to the truth of the
6 allegations in this paragraph of the Complaint regarding the amount in controversy, and,
7 therefore, deny them. However, Defendants admit that Plaintiff claims that the amount in
8 controversy exceeds \$75,000, exclusive of interests and costs.

9 7. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and
11 the amount in controversy, and, therefore, deny them. However, Defendants admit that Plaintiff
12 claims that the parties are diverse and that the amount in controversy exceeds \$75,000,
13 exclusive of interests and costs.

14 8. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding the judicial district in
16 which the asserted claims allegedly arose, and, therefore, deny them. Defendants deny any
17 wrongful conduct, deny committing a tort in the States of Mississippi or California, and deny
18 the remaining allegations in this paragraph of the Complaint.

19 9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
20 and co-promoted Bextra® in the United States, including Mississippi, to be prescribed by
21 healthcare providers who are by law authorized to prescribe drugs in accordance with their
22 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
23 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
24 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
25 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
26 admit that they provided FDA-approved prescribing information regarding Bextra®.
27 Defendants admit that they do business in the States of California and Mississippi. Defendants
28 state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.

1 Defendants are therefore without knowledge or information sufficient to form a belief as to the
2 truth of these allegations, and, therefore, deny them. Defendants deny any wrongful conduct
3 and deny the remaining allegations in this paragraph of the Complaint.

4 **Response to Factual Allegations**

5 10. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
7 condition and whether Plaintiff used Bextra®, and, therefore, deny them. Defendants deny that
8 Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this
9 paragraph of the Complaint.

10 11. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
12 condition and whether Plaintiff used Bextra®, and, therefore, deny them. Defendants state that
13 Bextra® was and is safe and effective when used in accordance with its FDA-approved
14 prescribing information. Defendants state that the potential effects of Bextra® were and are
15 adequately described in its FDA-approved prescribing information, which at all times was
16 adequate and comported with applicable standards of care and law. Defendants deny any
17 wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the
18 remaining allegations in this paragraph of the Complaint.

19 12. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
21 condition and whether Plaintiff used Bextra®, and, therefore, deny them. Defendants state that
22 Bextra® was and is safe and effective when used in accordance with its FDA-approved
23 prescribing information. Defendants state that the potential effects of Bextra® were and are
24 adequately described in its FDA-approved prescribing information, which at all times was
25 adequate and comported with applicable standards of care and law. Defendants deny any
26 wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the
27 remaining allegations in this paragraph of the Complaint.

28 13. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
2 Bextra®, and, therefore, deny them. Defendants admit that Bextra® was expected to reach
3 consumers without substantial change from the time of sale. Defendants deny the remaining
4 allegations in this paragraph of the Complaint.

5 14. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Bextra® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny the remaining allegations in this
12 paragraph of the Complaint.

13 15. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-
14 steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that the allegations in this
15 paragraph of the Complaint regarding aspirin and ibuprofen are not directed toward Defendants,
16 and, therefore, no response is required. To the extent that a response is deemed required,
17 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
18 paragraph of the Complaint regarding aspirin and ibuprofen. Defendants are therefore without
19 knowledge or information sufficient to form a belief as to the truth of these allegations, and,
20 therefore, deny the remaining allegations in this paragraph of the Complaint.

21 16. The allegations in this paragraph of the Complaint are not directed toward Defendants,
22 and, therefore, no response is required. To the extent that a response is deemed required,
23 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
24 paragraph of the Complaint. Defendants are therefore without knowledge or information
25 sufficient to form a belief as to the truth of these allegations, and, therefore, deny them.

26 17. The allegations in this paragraph of the Complaint are not directed toward Defendants,
27 and, therefore, no response is required. To the extent that a response is deemed required,
28 Defendants state that Plaintiff fails to provide the proper context for the allegations in this

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1 paragraph of the Complaint. Defendants are therefore without knowledge or information
2 sufficient to form a belief as to the truth of these allegations, and, therefore, deny them.

3 18. The allegations in this paragraph of the Complaint are not directed toward Defendants,
4 and, therefore, no response is required. To the extent that a response is deemed required,
5 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
6 paragraph of the Complaint. Defendants are therefore without knowledge or information
7 sufficient to form a belief as to the truth of these allegations, and, therefore, deny them.

8 19. The allegations in this paragraph of the Complaint are not directed toward Defendants,
9 and, therefore, no response is required. To the extent that a response is deemed required,
10 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
11 paragraph of the Complaint. Defendants are therefore without knowledge or information
12 sufficient to form a belief as to the truth of these allegations, and, therefore, deny them.

13 20. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
14 Complaint. Defendants are therefore without knowledge or information sufficient to form a
15 belief as to the truth of these allegations, and, therefore, deny them.

16 21. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are
17 vague and ambiguous. Defendants are therefore without knowledge or information sufficient to
18 form a belief as to the truth of these allegations, and, therefore, deny them. Defendants deny
19 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

20 22. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless,
21 Defendants admit that Celebrex® was launched in the United States in February 1999.
22 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
23 FDA-approved prescribing information. Defendants admit that, during certain periods of time,
24 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
25 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
26 with their approval by the FDA. Defendants admit that, during certain periods of time,
27 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
28 promoted and distributed Celebrex® in the United States to be prescribed by healthcare

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1 providers who are by law authorized to prescribe drugs in accordance with their approval by the
2 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not
3 directed toward Defendants, and, therefore, no response is required. To the extent that a
4 response is deemed required, Defendants state that Plaintiff fails to provide the proper context
5 for the allegations in this paragraph of the Complaint regarding Merck and Vioxx®.
6 Defendants are therefore without knowledge or information sufficient to form a belief as to the
7 truth of these allegations, and, therefore, deny them. Defendants deny the remaining allegations
8 in this paragraph of the Complaint.

9 23. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
10 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the
11 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
12 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.
13 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
14 ambiguous. Defendants are without knowledge or information sufficient to form a belief as to
15 the truth of these allegations, and, therefore, deny them. Defendants deny the remaining
16 allegations in this paragraph of the Complaint.

17 24. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.
18 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
19 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
20 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
21 allegations in this paragraph of the Complaint.

22 25. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
23 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
24 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
25 the remaining allegations in this paragraph of the Complaint.

26 26. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
27 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
28 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state

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1 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
2 prescribing information. Defendants state that the potential effects of Bextra® were and are
3 adequately described in its FDA-approved prescribing information, which at all times was
4 adequate and comported with applicable standards of care and law. Defendants deny the
5 remaining allegations in this paragraph of the Complaint.

6 27. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
8 Bextra®, and, therefore, deny them. Defendants admit that, during certain periods of time,
9 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed
10 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
11 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
12 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
13 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
14 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
15 state that Bextra® was and is safe and effective when used in accordance with its FDA-
16 approved prescribing information. Defendants state that the potential effects of Bextra® were
17 and are adequately described in its FDA-approved prescribing information, which at all times
18 was adequate and comported with applicable standards of care and law. Defendants state that
19 Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.
20 Defendants are without knowledge or information sufficient to form a belief as to the truth of
21 these allegations, and, therefore, deny them. Defendants deny any wrongful conduct and deny
22 the remaining allegations in this paragraph of the Complaint.

23 28. Defendants state that the referenced article speaks for itself and respectfully refer the
24 Court to the article for its actual language and full text. Any attempt to characterize the article
25 is denied. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
27 this paragraph of the Complaint.

28 29. The allegations in this paragraph of the Complaint are not directed toward Defendants,

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1 and, therefore, no response is required. To the extent that a response is deemed required,
2 Defendants state that the referenced article speaks for itself and respectfully refer the Court to
3 the article for its actual language and full text. Any attempt to characterize the article is denied.
4 Defendants deny the remaining allegations in this paragraph of the Complaint.

5 30. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
6 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November
7 16, 2001. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
9 the remaining allegations in this paragraph of the Complaint.

10 31. Defendants state that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants deny the allegations in this
12 paragraph of the Complaint.

13 32. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and
14 respectfully refer the Court to the Talk Paper for its actual language and full text. Any attempt
15 to characterize the Talk Paper is denied. Defendants deny the remaining allegations in this
16 paragraph of the Complaint.

17 33. Defendants state that the referenced article speaks for itself and respectfully refer the
18 Court to the article for its actual language and full text. Any attempt to characterize the article
19 is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 34. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
21 Complaint regarding the “post-drug approval meta-analysis study.” Defendants are therefore
22 without knowledge or information sufficient to form a belief as to the truth of these allegations,
23 and, therefore, deny them. Defendants state that the referenced study speaks for itself and
24 respectfully refer the Court to the study for its actual language and full text. Any attempt to
25 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
26 the Complaint.

27 35. The allegations in this paragraph of the Complaint are not directed toward Defendants,
28 and, therefore, no response is required. To the extent that a response is deemed required,

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1 Defendants state that the referenced article speaks for itself and respectfully refer the Court to
2 the article for its actual language and full text. Any attempt to characterize the article is denied.
3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 36. The allegations in this paragraph of the Complaint are not directed toward Defendants,
5 and, therefore, no response is required. To the extent that a response is deemed required,
6 Defendants admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety
7 and Risk Management Advisory Committee was held on February 16-18, 2005. Defendants
8 state that the referenced testimony speaks for itself and respectfully refer the Court to the
9 testimony for its actual language and full text. Any attempt to characterize the testimony is
10 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 37. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
13 deny the remaining allegations in this paragraph of the Complaint.

14 38. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
15 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
16 and full text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 39. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
19 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
20 and full text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 40. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants deny the allegations in this
24 paragraph of the Complaint.

25 41. Defendants state that the referenced article speaks for itself and respectfully refer the
26 Court to the article for its actual language and full text. Any attempt to characterize the article
27 is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
28 paragraph of the Complaint.

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1 42. The allegations in this paragraph of the Complaint are not directed toward Defendants,
2 and, therefore, no response is required. To the extent that a response is deemed required,
3 Defendants state that the referenced article speaks for itself and respectfully refer the Court to
4 the article for its actual language and full text. Any attempt to characterize the article is denied.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 43. Defendants state that the referenced PDR entry speaks for itself and respectfully refer
8 the Court to the PDR entry for its actual language and full text. Any attempt to characterize the
9 PDR entry is denied. Defendants state that Bextra® was and is safe and effective when used in
10 accordance with its FDA-approved prescribing information. Defendants state that the potential
11 effects of Bextra® were and are adequately described in its FDA-approved prescribing
12 information, which was at all times adequate and comported with applicable standards of care
13 and law. Defendants deny the allegations in this paragraph of the Complaint.

14 44. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
19 allegations in this paragraph of the Complaint.

20 45. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
25 the Complaint.

26 46. Defendants deny the allegations in this paragraph of the Complaint.

27 47. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Bextra® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
6 allegations in this paragraph of the Complaint.

7 48. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
9 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
11 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
12 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
13 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Bextra® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny the remaining allegations in this
18 paragraph of the Complaint.

19 49. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
20 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
21 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
22 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
23 prescribing information. Defendants state that the potential effects of Bextra® were and are
24 adequately described in its FDA-approved prescribing information, which was at all times
25 adequate and comported with applicable standards of care and law. Defendants deny the
26 remaining allegations in this paragraph of the Complaint.

27 50. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which at all times was adequate and comported with applicable standards of care and law.
3 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
4 ambiguous. Defendants are without knowledge or information sufficient to form a belief as to
5 the truth of these allegations, and, therefore, deny them. Defendants deny any wrongful
6 conduct, deny that Bextra® is defective, and deny the allegations in this paragraph of the
7 Complaint.

8 51. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
9 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
10 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
11 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
12 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
13 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
14 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Bextra® were and are adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants deny the remaining allegations in this
19 paragraph of the Complaint.

20 52. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which at all times was adequate and comported with applicable standards of care and law.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 53. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 54. Defendants state that Bextra® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Bextra® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.

7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 55. Defendants deny the allegations in this paragraph of the Complaint.

10 56. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market
11 as of April 7, 2005. Defendants deny any wrongful conduct and deny the remaining allegations
12 contained in this paragraph of the Complaint.

13 57. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.

17 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
18 allegations in this paragraph of the Complaint.

19 58. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.

23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 59. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint.

27 60. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Bextra® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint.

7 61. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Bextra®, and, therefore, deny them. Defendants admit that, during certain periods of time,
10 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed
11 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
12 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
13 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
14 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
15 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
16 deny the remaining allegations in this paragraph of the Complaint.

17 62. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
18 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
19 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
20 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
21 prescribing information. Defendants state that the potential effects of Bextra® were and are
22 adequately described in its FDA-approved prescribing information, which was at all times
23 adequate and comported with applicable standards of care and law. Defendants deny any
24 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

25 63. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

1 state that the potential effects of Bextra® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants state that Plaintiff's allegations regarding
4 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
5 information sufficient to form a belief as to the truth of these allegations, and, therefore, deny
6 them. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
7 dangerous, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining
8 allegations in this paragraph of the Complaint.

9 **Response to First Cause of Action: Negligence**

10 64. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
11 Complaint as if fully set forth here.

12 65. Defendants state that this paragraph of the Complaint contains legal contentions to
13 which no response is deemed required. To the extent that a response is deemed required,
14 Defendants admit that they had duties as are imposed by law but deny having breached those
15 duties. Defendants state that the potential effects of Bextra® were and are adequately described
16 in its FDA-approved prescribing information, which was at all times adequate and comported
17 with applicable standards of care and law. Defendants state that Bextra® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 deny the remaining allegations in this paragraph of the Complaint.

20 66. Defendants state that this paragraph of the Complaint contains legal contentions to
21 which no response is deemed required. To the extent that a response is deemed required,
22 Defendants admit that they had duties as are imposed by law but deny having breached those
23 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28 67. Defendants state that this paragraph of the Complaint contains legal contentions to

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1 which no response is required. To the extent that a response is deemed required, Defendants
2 admit that they had duties as are imposed by law but deny having breached those duties.
3 Defendants state that Bextra® was and is safe and effective when used in accordance with its
4 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
5 were and are adequately described in its FDA-approved prescribing information, which was at
6 all times adequate and comported with applicable standards of care and law. Defendants deny
7 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,
8 including all subparts.

9 68. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
11 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Bextra® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
16 Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the
17 Complaint.

18 69. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 70. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
26 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
27 effective when used in accordance with its FDA-approved prescribing information. Defendants
28 state that the potential effects of Bextra® were and are adequately described in its FDA-

1 approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
3 Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this
4 paragraph of the Complaint.

5 71. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
6 damages, and deny the remaining allegations in this paragraph of the Complaint.

7 72. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
8 damages, and deny the remaining allegations in this paragraph of the Complaint.

9 73. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
10 damages, and deny the remaining allegations in this paragraph of the Complaint.

11 **Response to Second Cause of Action: Strict Liability**

12 74. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
13 Complaint as if fully set forth here.

14 75. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Bextra®, and, therefore, deny them. Defendants admit that Bextra® was expected to reach
17 consumers without substantial change in the condition from the time of sale. Defendants admit
18 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra®
19 in the United States to be prescribed by healthcare providers who are by law authorized to
20 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during
21 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,
22 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by
23 healthcare providers who are by law authorized to prescribe drugs in accordance with their
24 approval by the FDA. Defendants state that Bextra® was and is safe and effective when used
25 in accordance with its FDA-approved prescribing information. Defendants state that the
26 potential effects of Bextra® were and are adequately described in its FDA-approved prescribing
27 information, which was at all times adequate and comported with applicable standards of care
28 and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 76. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 77. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
12 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

13 78. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and
18 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

19 79. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and
24 deny the remaining allegations in this paragraph of the Complaint.

25 80. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Bextra® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
4 Bextra® is defective, deny that Bextra® caused Plaintiff injury or damages, and deny the
5 remaining allegations in this paragraph of the Complaint.

6 81. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
11 allegations in this paragraph of the Complaint.

12 82. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
14 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Bextra® were and are adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
19 Bextra® is defective, deny that Bextra® caused Plaintiff injury or damages, and deny the
20 remaining allegations in this paragraph of the Complaint.

21 83. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 84. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
28 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and

1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Bextra® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
5 remaining allegations in this paragraph of the Complaint.

6 85. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 86. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
17 allegations in this paragraph of the Complaint.

18 87. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
19 damages, and deny the remaining allegations in this paragraph of the Complaint.

20 88. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
21 damages, and deny the remaining allegations in this paragraph of the Complaint.

22 89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
23 damages, and deny the remaining allegations in this paragraph of the Complaint.

24 **Response to Third Cause of Action: Breach of Express Warranty**

25 90. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
26 Complaint as if fully set forth here.

27 91. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Bextra® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants admit that they provided FDA-approved
6 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this
7 paragraph of the Complaint.

8 92. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
10 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Bextra® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants admit that they provided FDA-approved
15 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this
16 paragraph of the Complaint, including all subparts.

17 93. Defendants deny the allegations in this paragraph of the Complaint.

18 94. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants admit that they provided FDA-approved prescribing information regarding
23 Bextra®. Defendants deny any wrongful conduct and deny the remaining allegations in this
24 paragraph of the Complaint.

25 95. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

1 Defendants admit that they provided FDA-approved prescribing information regarding
2 Bextra®. Defendants deny any wrongful conduct and deny the remaining allegations in this
3 paragraph of the Complaint.

4 96. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Bextra®, and, therefore, deny them. Defendants admit that they provided FDA-approved
7 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this
8 paragraph of the Complaint.

9 97. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
10 damages, and deny the remaining allegations in this paragraph of the Complaint.

11 98. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
12 damages, and deny the remaining allegations in this paragraph of the Complaint.

13 99. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
14 damages, and deny the remaining allegations in this paragraph of the Complaint.

15 **Response to Fourth Cause of Action: Breach of Implied Warranty**

16 100. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
17 Complaint as if fully set forth here.

18 101. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
19 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
20 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
21 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
22 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
23 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
24 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
25 paragraph of the Complaint.

26 102. Defendants admit that they provided FDA-approved prescribing information regarding
27 Bextra®. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 103. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Bextra®, and, therefore, deny them. Defendants admit, as indicated in the package insert
7 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
8 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
9 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 104. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Bextra® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny the remaining allegations in this
17 paragraph of the Complaint.

18 105. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Bextra®, and, therefore, deny them. Defendants state that Bextra® was expected to reach
21 consumers without substantial change in the condition from the time of sale. Defendants deny
22 the remaining allegations in this paragraph of the Complaint.

23 106. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
28 Complaint.

1 107. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
2 damages, and deny the remaining allegations in this paragraph of the Complaint.

3 108. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
4 damages, and deny the remaining allegations in this paragraph of the Complaint.

5 109. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
6 damages, and deny the remaining allegations in this paragraph of the Complaint.

7 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

8 110. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
9 Complaint as if fully set forth here.

10 111. Defendants state that this paragraph of the Complaint contains legal contentions to
11 which no response is deemed required. To the extent that a response is deemed required,
12 Defendants admit that they had duties as are imposed by law but deny having breached those
13 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 112. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint, including all subparts.

24 113. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

1 the Complaint.

2 114. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Bextra® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
9 Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
10 paragraph of the Complaint.

11 115. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 116. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 117. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Bextra® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

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1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
2 remaining allegations in this paragraph of the Complaint.

3 118. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
5 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Bextra® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
10 remaining allegations in this paragraph of the Complaint.

11 119. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
13 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Bextra® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 120. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 121. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

1 state that the potential effects of Bextra® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 122. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
6 damages, and deny the remaining allegations in this paragraph of the Complaint.

7 123. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
8 damages, and deny the remaining allegations in this paragraph of the Complaint.

9 124. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
10 damages, and deny the remaining allegations in this paragraph of the Complaint.

11 **Response to Sixth Cause of Action: Unjust Enrichment**

12 125. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
13 Complaint as if fully set forth here.

14 126. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
15 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
16 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
17 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
18 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
19 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
20 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 127. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
24 Bextra®, and, therefore, deny them. Defendants deny the remaining allegations in this
25 paragraph of the Complaint.

26 128. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
28 Bextra®, and, therefore, deny them. Defendants deny the remaining allegations in this

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1 paragraph of the Complaint.

2 129. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Bextra® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny the remaining allegations in this
9 paragraph of the Complaint.

10 130. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Bextra®, and, therefore, deny them. Defendants state that Bextra® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Bextra® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
17 Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this
18 paragraph of the Complaint.

19 131. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
20 damages, and deny the remaining allegations in this paragraph of the Complaint.

21 **Response to Prayer for Relief**

22 132. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
23 damages, and deny the remaining allegations in this paragraph of the Complaint.

24 133. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
25 damages, and deny the remaining allegations in this paragraph of the Complaint.

26 134. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
27 damages, and deny the remaining allegations in this paragraph of the Complaint.

28 135. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or

1 damages, and deny the remaining allegations in this paragraph of the Complaint.

2 136. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
3 damages, and deny the remaining allegations in this paragraph of the Complaint.

4 137. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
5 damages, and deny the remaining allegations in this paragraph of the Complaint.

6 138. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
7 damages, and deny the remaining allegations in this paragraph of the Complaint.

8 139. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
9 damages, and deny the remaining allegations in this paragraph of the Complaint.

10 **III.**

11 **GENERAL DENIAL**

12 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's
13 Complaint that have not been previously admitted, denied, or explained.

14 **IV.**

15 **AFFIRMATIVE DEFENSES**

16 Defendants reserve the right to rely upon any of the following or additional defenses to
17 claims asserted by Plaintiff to the extent that such defenses are supported by information
18 developed through discovery or evidence at trial. Defendants affirmatively show that:

19 **First Defense**

20 1. The Complaint fails to state a claim upon which relief can be granted.

21 **Second Defense**

22 2. Bextra® is a prescription medical product. The federal government has preempted the
23 field of law applicable to the labeling and warning of prescription medical products.
24 Defendants' labeling and warning of Bextra® was at all times in compliance with applicable
25 federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon
26 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
27 and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information, and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pleaded in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily negligent, actively negligent, or otherwise failed to mitigate Plaintiff's damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use, and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred, in whole or in part, by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff's alleged injuries/damages, if any, were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*

Twenty-first Defense

21. Plaintiff's claims are barred, in whole or in part, under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution, and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred, in whole or in part, by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred, in whole or in part, because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred, in whole or in part, because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred, in whole or in part, because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and Constitutions of the States of Mississippi, Arizona, and California, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution and the Constitutions of the States of Mississippi, Arizona, and California.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading, and,

1 therefore, constitute protected commercial speech under the applicable provisions of the United
2 States Constitution.

3 **Thirty-eighth Defense**

4 38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly
5 caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable
6 law or statute or, in the alternative, are unconstitutional insofar as they violate the due process
7 protections afforded by the United States Constitution, the excessive fines clause of the Eighth
8 Amendment of the United States Constitution, the Commerce Clause of the United States
9 Constitution, and the Full Faith and Credit Clause of the United States Constitution and the
10 Constitutions of the States of Mississippi, Arizona, and California. Any law, statute, or other
11 authority purporting to permit the recovery of punitive damages in this case is unconstitutional,
12 facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally
13 sufficient standards to guide and restrain the jury's discretion in determining whether to award
14 punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide
15 adequate advance notice as to what conduct will result in punitive damages; (3) permits
16 recovery of punitive-damages based on out-of-state conduct, conduct that complied with
17 applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff;
18 (4) permits recovery of punitive damages in an amount that is not both reasonable and
19 proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory
20 damages, if any; (5) permits jury consideration of net worth or other financial information
21 relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial
22 court in post-verdict review of any punitive damages awards; (7) lacks constitutionally
23 sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to
24 satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v.*
25 *Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443
26 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto*
27 *Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured, and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases, or illnesses, subsequent medical conditions, or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards, and regulations established, adopted, promulgated, or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of Plaintiff and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation, fraud, and concealment allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. To the extent that Plaintiff relies upon any theory of breach of warranty, Plaintiff's claims are barred because Defendants did not make or breach any express or implied warranties, and Plaintiff failed to give reasonable notice to Defendants of any alleged breach or breaches of warranty as required by Miss. Code Ann. § 75-2-607(3)(a).

Fifty-ninth Defense

59. Any verdict or judgment rendered against Defendants must be reduced under the laws of the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiff, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiff may have settled his claims for alleged injuries and damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiff and any such parties.

Sixtieth Defense

60. Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damage awards which arise under the United States Constitution and decisions of the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi Constitution, statutes, and decisions of Mississippi courts.

Sixty-first Defense

61. Defendants assert that Plaintiff's claim for punitive damages is governed and limited by Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the same.

Sixty-second Defense

62. Bextra® and the Defendants' actions conformed to the state-of-the-art medical and scientific knowledge at all times relevant to this lawsuit and/or Bextra® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

Sixty-third Defense

63. Defendants satisfied their duty to warn under the learned intermediary doctrine and Plaintiff's claims are therefore barred.

Sixty-fourth Defense

64. Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

Sixty-fifth Defense

65. Defendants hereby invoke the limitations and provisions of Miss. Code Ann. § 11-1-60.

Sixty-sixth Defense

66. Plaintiff failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already parties to the action and will result in prejudice to Defendants in any possible future litigation.

Sixty-seventh Defense

67. Any judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to warn, are unconstitutional in that, among other things, they are void for vagueness and undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

Sixty-eighth Defense

68. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any award of punitive damages is barred.

Sixty-ninth Defense

69. Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks standing to bring such claims.

Seventieth Defense

70. Plaintiff's claims are barred in whole or in part by the affirmative defenses referenced in A.R.S. § 12-683.

Seventy-first Defense

71. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff takes nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

August 13, 2008

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

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